

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 30, 2020

Findings Date: April 30, 2020

Project Analyst: Tanya M. Saporito

Team Leader: Gloria C. Hale

Project ID #: L-11838-20

Facility: Edgecombe Home Dialysis

FID #: 150397

County: Edgecombe

Applicant: FMS ENA Home, LLC

Project: Relocate no more than one dialysis station from BMA East Rocky Mount for home hemodialysis training and support services

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

FMS ENA Home, LLC (hereinafter referred to as “applicant” or “FMS”) proposes to relocate one existing dialysis station from BMA East Rocky Mount to Edgecombe Home Dialysis, an existing standalone kidney disease treatment center offering peritoneal dialysis (PD) training and support, for the provision of home hemodialysis (HHD) training and support.

Need Determination

The applicant does not propose to increase the number of licensed beds in any category, add any new health services, or acquire equipment for which there is a need determination in the 2020 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2020 SMFP that are applicable to this review.

Policies

There is one policy in the 2020 SMFP which is applicable to this review:

Policy ESRD-2: Relocation of Dialysis Stations, on page 20 of the 2020 SMFP, states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 2. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

Both Edgecombe Home Dialysis and BMA East Rocky Mount are located in Edgecombe County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

BMA proposes to relocate one existing dialysis station from BMA East Rocky Mount to Edgecombe Home Dialysis, an existing standalone kidney disease treatment center offering peritoneal dialysis (PD) training and support, for the provision of home hemodialysis (HHD) training and support.

Edgecombe Home Dialysis was first certified in 2017 as a freestanding kidney disease treatment center to provide exclusively PD patient training and support. Because PD patient training does not involve the use of dialysis stations, there are currently no stations at the existing facility.

In this application, the applicant proposes to relocate one existing dialysis station that is used exclusively for in-center dialysis, from BMA East Rocky Mount to Edgecombe Home Dialysis.

Patient Origin

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the county in which the dialysis station is located.*” Thus, the service area is Edgecombe County. Facilities may serve residents of counties not included in their service area.

In Section C.2, pages 17 – 18, the applicant provides current and projected patient origin for Edgecombe Home Dialysis. The applicant states current patient origin is based on the last full Operating Year (OY), calendar year (CY) 2019. See the following table that combines the applicant’s data:

Edgecombe Home Dialysis Current and Projected Patient Origin

| COUNTY | CURRENT (LAST FULL OY – CY 2019) | | | PROJECTED (OY 2 – CY 2022) | | | |
|--------------|----------------------------------|------------------|----------------|----------------------------|----------------|------------------|----------------|
| | # OF HH PATIENTS | # OF PD PATIENTS | # OF TOTAL | # OF HH PATIENTS | # OF TOTAL | # OF PD PATIENTS | # OF TOTAL |
| Edgecombe | 0 | 15 | 42.86% | 4.7 | 100.00% | 17.5 | 50.74% |
| Bertie | 0 | 4 | 11.43% | 0 | 0.00% | 4 | 11.59% |
| Greene | 0 | 1 | 2.86% | 0 | 0.00% | 1 | 2.90% |
| Halifax | 0 | 1 | 2.86% | 0 | 0.00% | 1 | 2.90% |
| Hertford | 0 | 2 | 5.71% | 0 | 0.00% | 0 | 0.00% |
| Martin | 0 | 3 | 8.57% | 0 | 0.00% | 3 | 8.69% |
| Nash | 0 | 4 | 11.43% | 0 | 0.00% | 4 | 11.59% |
| Pitt | 0 | 1 | 2.86% | 0 | 0.00% | 1 | 2.90% |
| Wake | 0 | 1 | 2.86% | 0 | 0.00% | 1 | 2.90% |
| Washington | 0 | 2 | 5.71% | 0 | 0.00% | 2 | 5.79% |
| Wilson | 0 | 1 | 2.86% | 0 | 0.00% | 0 | 0.00% |
| Total | 0 | 35 | 100.00% | 4.7 | 100.00% | 34.5 | 100.00% |

Source: Section C, pages 17 – 18
 Numbers may not sum due to rounding

In Section C, pages 18 - 21, the applicant provides the assumptions and methodology it used to project patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

“This application is primarily focused on relocating one dialysis station to Edgecombe Home Dialysis to be utilized exclusively for home hemodialysis training and support.

Home dialysis patients – PD and home hemodialysis – require the same regular dialysis treatment regimen. Home PD patients may dialyze on a continuing basis (Continuous Ambulatory Peritoneal Dialysis, or CAPD) or the patients may use a cyclor which is a machine that helps the patient to dialyze overnight. Home hemodialysis patients may use the traditional home hemodialysis regimen of three treatments per week, or as is becoming more and more routine, the home hemodialysis patient may be dialyzing more frequently for shorter periods of time. Some home hemodialysis patients may dialyze as often as six times per week....

...

Dialysis schedules at times which are not convenient for the patient will adversely affect patient compliance and lead to higher missed treatment rates. Home dialysis affords the patient maximum flexibility with scheduling treatment at times which are convenient, and in the patient residence. The patient has total control of the treatment.

Dialysis in a setting which is not convenient for the patient, similarly leads to patient compliance issues and higher missed treatment rates.

Approval of this application will allow the applicant to relocate one hemodialysis station to be used for home training and support program [sic] of patients choosing hemo dialysis. This will enhance patient training opportunities and ultimately will allow Edgecombe Home Dialysis to enable more patients to dialyze at home in a convenient setting, at times which are convenient for the patient.”

In Section C, pages 22 - 24, the applicant explains the process of home dialysis training, the space that is needed, and the time it takes to successfully train patients to dialyze at home. The applicant states that there is a national emphasis on home training for dialysis patients, and neither the applicant nor its parent, Fresenius Medical Care has another facility in Edgecombe County that has space available to accommodate home training patients. The applicant states on page 24 that adding one station at the existing Edgecombe Home Dialysis to be used for training and support for home hemodialysis patients will allow Edgecombe County residents to receive home hemodialysis training at a facility within the county, and will eliminate the need for those patients to travel outside the county for the needed service. In addition, in Exhibit H.4, the applicant provides a letter from the medical director of Eastern Nephrology

Associates, the nephrology practice that refers patients in Edgecombe County to the applicant or its parent entity, which states:

“Relocating one dialysis station to Edgecombe Home Dialysis will allow the facility to offer home hemodialysis training and support services. At the present time this modality is not available within Edgecombe County. Consequently, Edgecombe County dialysis patients desiring to dialyze by home hemodialysis must first, go out of county for their training, and then secondly, go out of county for monthly visits with the home training staff. This is a significant disadvantage to the home hemodialysis patient.”

The information is reasonable and adequately supported because the applicant adequately explains the need that Edgecombe County dialysis patients who elect home hemodialysis training and support have for a home hemodialysis training and support program in a single location within the county.

Projected Utilization

In Section Q, pages 75 - 76, the applicant provides historical and projected utilization as illustrated in the following tables:

Edgecombe Home Dialysis PD Patients as of December 31, 2019

| COUNTY | # PTS. AS OF 12/31/19 |
|--------------|-----------------------|
| Edgecombe | 15 |
| Bertie | 4 |
| Greene | 1 |
| Halifax | 1 |
| Hertford | 2 |
| Martin | 3 |
| Nash | 4 |
| Pitt | 1 |
| Wake | 1 |
| Washington | 2 |
| Wilson | 1 |
| Total | 35 |

Source: Section Q, page 75

Edgecombe Home Dialysis Projected HHD and PD Patients

| | OY 1 (CY 2021) | | OY 2 (CY 2022) | |
|----------------|----------------|---------|----------------|---------|
| | HHD PTS. | PD PTS. | HHD PTS. | PD PTS. |
| Total Patients | 4.4 | 33.6 | 4.7 | 34.5 |

Source: Section C, page 76

In Section C, pages 18 – 21 Section Q, pages 73 – 76 and in supplemental information, the applicant provides the assumptions and methodology it used to project HH and PD patient utilization, which are summarized below.

Home Hemodialysis Patients

- The applicant states this facility is not currently certified to provide home hemodialysis training and services but recognizes a surge in patient and physician interest in home hemodialysis services.
- The applicant states that, as of June 30, 2019, there were “*at least six home hemodialysis patients*” in Edgecombe County who are currently served by BMA: two patients were being served by FMC South Rocky Mount and four patients were being served by Greenville Dialysis Center.
- The applicant states four Edgecombe County home hemodialysis patients are patients of Eastern Nephrology Associates (ENA), and the physicians associated with ENA admit and follow PD patients currently served by Edgecombe Home Dialysis. Additionally, the applicant states the medical director for Edgecombe Home Dialysis is associated with ENA.
- The applicant assumes, therefore, that the home hemodialysis patients residing in Edgecombe County who are followed by nephrologists at ENA will transfer their care to Edgecombe Home Dialysis when the facility is certified to provide home hemodialysis services.
- The applicant explains that home hemodialysis patients visit the dialysis facility once per month for training, support and counseling on the home hemodialysis treatment regimen. The patients meet with their nephrologist at these visits, which can last several hours. The applicant states that patients prefer to schedule such appointments in a facility that is close to their residence.
- The applicant states that, since the nephrologists of ENA currently treat existing home hemodialysis patients in other facilities owned by the applicant, those nephrologists will likely refer additional home hemodialysis patients to Edgecombe Home Dialysis when it is certified for such training. The applicant states it is already experiencing a surge in referrals for home dialysis in all of its facilities.
- The applicant begins its projections of home hemodialysis patients with the four patients currently followed by ENA who reside in Edgecombe County, as reported in the February ESRD Data Collection Form submitted to the Agency.
- The applicant states the project is scheduled for completion by December 31, 2020 and the first two operating years are as follows:
 - OY 1: Calendar year 2021
 - OY 2: Calendar year 2022

Following is a table from page 75 that illustrates the applicant’s projected utilization calculations, using the 5.3% Five Year Average Annual Change Rate (AACR) for Edgecombe County as published in the 2020 SMFP:

| | |
|--|--------------------------|
| Begin with census of Edgecombe County home hemodialysis patients followed by ENA as of 12/31/19. | 4 |
| Project forward one year to 12/31/20 using the 5.3% Edgecombe County Five Year AACR. | $4 \times 1.053 = 4.2$ |
| Project forward one year to 12/31/21 using the 5.3% Edgecombe County Five Year AACR. This is the projected ending census of home hemodialysis patients for OY 1. | $4.2 \times 1.053 = 4.4$ |
| Project forward one year to 12/31/22 using the 5.3% Edgecombe County Five Year AACR. This is the projected ending census of home hemodialysis patients for OY 2. | $4.4 \times 1.053 = 4.7$ |

Peritoneal Dialysis Patients

- The applicant begins with the facility census of 35 PD patients at Edgecombe Home Dialysis as of December 31, 2019.
- The applicant projects growth in the PD patient population using the Edgecombe County Five Year AACR of 5.3%. The applicant states “*Of the 30 patients at the facility on December 31, 2019, 15 were residents of Edgecombe County.*” The ESRD Data Collection Form confirms that 35 PD patients are followed at this facility, and that 15 are residents of Edgecombe County.
- The applicant states the facility was also serving two PD patients who are residents of Hertford County and one PD patient who is a resident of Wilson County. The applicant states it does not project future growth of these three patients at this facility, because it plans to file applications to develop home programs in both Hertford and Wilson counties.
- The applicant states it does not project growth from other patients residing in other counties but assumes those patients will continue to receive care at the facility and will add them to the growth projections at appropriate points in time.
- The applicant assumes the nephrologists at ENA will continue to refer more patients to Edgecombe Home Dialysis.
- The project is scheduled for completion on December 31, 2020, and first two operating years are as follows:
 - OY 1: Calendar year 2021
 - OY 2: Calendar year 2022

The following table illustrates projected PD patient census for OY 1 and OY 2, from Sections C and Q:

| | |
|--|----------------------------|
| Begin with census of Edgecombe County home PD patients as of 12/31/19. | 15 |
| Project forward one year to 12/31/20 using the 5.3% Edgecombe County Five Year AACR. | $15 \times 1.053 = 15.8$ |
| Add the 20 patients residing in other counties. | $15.8 + 20 = 35.8$ |
| Subtract the Hertford and Wilson county patients. This is the projected starting PD patient census for this project. | $35.8 - 3 = 32.8$ |
| Project Edgecombe County patient population forward one year to 12/31/21 using the 5.3% Edgecombe County Five Year AACR. | $15.8 \times 1.053 = 16.6$ |
| Add the 17 patients residing in other counties. This is the projected ending census for OY 1. | $16.6 + 17 = 33.6$ |
| Project Edgecombe County patient population forward one year to 12/31/22 using the 5.3% Edgecombe County Five Year AACR. | $16.6 \times 1.053 = 17.5$ |
| Add the 17 patients residing in other counties. This is the projected ending census for OY 2. | $17.5 + 17 = 34.5$ |

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant projects future PD patient utilization based on historical utilization.
- The applicant projects future HHD patient utilization based on existing HHD patients being followed by the physicians at ENA and another facility owned by the applicant.
- The applicant uses the Five Year AACR for Edgecombe County as published in the 2020 SMFP to project growth of Edgecombe County HHD and PD patients.

Access

In Section C, page 26, the applicant states:

“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

In Section L, page 54, the applicant projects the payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table:

| EDGECOMBE HOME DIALYSIS PROJECTED PAYOR MIX CY 2022 | | |
|---|----------------|----------------|
| PAYMENT SOURCE | % HH PATIENTS | % PD PATIENTS |
| Self-Pay | 0.62% | 2.44% |
| Insurance* | 18.20% | 39.37% |
| Medicare* | 65.74% | 44.42% |
| Medicaid* | 3.26% | 3.69% |
| Medicare/Commercial | 7.69% | 8.25% |
| Misc. (including VA) | 4.48% | 1.83% |
| Total | 100.00% | 100.00% |

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency
- Supplemental information requested by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

BMA proposes to relocate one existing dialysis station from BMA East Rocky Mount to Edgecombe Home Dialysis, an existing standalone kidney disease treatment center offering peritoneal dialysis (PD) training and support, for the provision of home hemodialysis (HHD) training and support.

In Section D, page 35, the applicant states:

“This is an application to relocate a single dialysis station from BMA East Rocky Mount to Edgecombe Home Dialysis. The station will be used to provide home dialysis training and support for patients desiring home hemodialysis as their dialysis modality.

The Edgecombe Home Dialysis facility is currently certified to provide peritoneal dialysis training and support services. A dialysis station is not necessary to provide peritoneal dialysis training and support. However, a dialysis station is absolutely necessary to provide hemodialysis training services.

...

Of the Fresenius related facilities in the county, only Edgecombe Home Dialysis offers home training. And, Edgecombe Home Dialysis does not have a dialysis station and therefore cannot offer home hemodialysis training and support services. Thus, if Fresenius Medical Care is to offer home hemodialysis within Edgecombe County, the only option is to relocate a station from BMA East Rocky Mount, and dedicate that station to providing home hemodialysis training and support services.”

According to the 2020 SMFP, BMA East Rocky Mount had 30 certified stations as of December 31, 2018. There are five projects involving BMA East Rocky Mount, three of which were previously approved but are still under development as of the date of these findings. The three approved projects are:

- Project ID #L-11483-18 (Add four stations)
- Project ID #L-11580-18 (Add two stations)
- Project ID #L-11374-17 (relocate 10 stations)

Two projects, Project ID#L-11876-20 (add 9 stations) and Project ID #L-11839-20 (relocate 4 stations) are currently under review.

As of the date of these findings, BMA East Rocky Mount is certified for 30 dialysis stations. Including only the approved projects listed above and this project, BMA East Rocky Mount will have 25 certified stations. In Section D, page 31, the applicant states the physical capacity of BMA East Rocky Mount is 30 stations. Therefore, if this project and the two projects currently under review are approved, there will be no net gain or loss of stations available to the in-center patient population at BMA East Rocky Mount ($25 - 4 + 9 = 30$).

In Section D, pages 30 - 33, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated, or relocated will be adequately met following completion of the project. On page 30, the applicant states:

“The patients remaining at BMA East Rocky Mount will not be adversely impacted by this proposal. The 2020 SMFP indicates that BMA East Rocky Mount qualifies to apply for up to 11 additional dialysis stations in 2020.”

The applicant filed an application in March 2020 to add nine stations to BMA East Rocky Mount. That application is currently under review. On pages 32 - 33, the applicant states that by adding nine stations, no patients at BMA East Rocky Mount will be denied dialysis services as a result of this application.

In Section D, pages 31 - 32, the applicant provides the assumptions and methodology used to project utilization, as summarized below.

- Using data provided to the Agency in the February 2020 ESRD Data Collection Forms, the applicant states it begins its projections with the number of in-center patients dialyzing at BMA East Rocky Mount, as shown in the table below:

| COUNTY | # OF PATIENTS DECEMBER 31, 2019 |
|--------------|------------------------------------|
| Edgecombe | 78 |
| Halifax | 3 |
| Nash | 31 |
| Warren | 1 |
| Total | 113 |

- The applicant projects the Edgecombe County patient population will grow by 5.3%, which is the Five Year AACR for Edgecombe County as published in the 2020 SMFP.
- The applicant states that, as part of Project I.D. #L-11374-17 (develop a new 10-station dialysis facility, FKC Boice-Willis), it projects 32 Edgecombe County patients from BMA East Rocky Mount will transfer care to FKC Boice-Willis once it opens, and subtracts those 32 patients from the calculations as of December 31, 2020 (the projected completion date for FKC Boice-Willis).
- The applicant states the facility was serving 31 patients from Nash County as of December 31, 2019, which is equal to 27.43% of the total facility census. The applicant projects growth of the Nash County patient population using the Nash County Five Year AACR of 1.1%.
- The applicant states it was serving four additional patients at FKC Rocky Mount who reside in Halifax and Warren counties. The applicant will not project growth of that patient population and will add them to the patient census at the appropriate time.

- The applicant projects project completion by December 31, 2020 and projects the patient census of BMA East Rocky Mount to that date.

In Section D, page 32, the applicant projects in-center patient utilization of BMA East Rocky Mount following completion of the proposed project, as shown in the table below.

| | Edgecombe County | Nash County |
|--|----------------------------|---------------------------|
| Begin with the facility census of Edgecombe and Nash county patients as of December 31, 2019. | 78 | 31 |
| Project forward one year to December 31, 2020, using each county's Five Year AACR (5.3% in Edgecombe County, 1.1% in Nash County). | $78 \times 1.053 = 82.13$ | $31 \times 1.011 = 31.34$ |
| Subtract 32 Edgecombe County patients projected to transfer to FKC Boice-Willis (Project ID# L-11374-17). | $82.13 - 32 = 50.13$ | 31.34 |
| Add Edgecombe and Nash county patients and add the patients residing in other counties. This is the projected census for December 31, 2020, the date the stations are projected to be relocated. | $50.13 + 31.34 + 4 = 85.5$ | |

Numbers may not sum due to rounding by project analyst.

The applicant projects to serve 85.5 patients on 25 in-center stations, which is 3.42 patients per station per week ($85.5 \text{ patients} / 25 \text{ stations} = 3.42$), for a utilization rate of 85.5% by the beginning of OY 1.

On pages 31 – 32, the applicant reiterates that it filed an application to add nine stations to BMA East Rocky Mount on March 1, 2020. The applicant states the patients dialyzing at BMA East Rocky Mount will not be adversely affected by the relocation of the one station as proposed in this application.

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant uses the Five Year AACR for Edgecombe and Nash counties as published in the 2020 SMFP to project patient utilization in each of those counties.
- The applicant accounts for patients who are proposed to transfer care to a different facility as part of projects under development.
- The applicant accounts for projects currently under development.
- The applicant accounts for the additional station need at BMA East Rocky Mount.

In Section D, page 32, the applicant states the proposed relocation of one station will have no effect on the ability of patients using the existing facility, including low income patients, women, disabled patients, and other underserved patients, to access services, and states it makes dialysis services available to all residents of the service area without qualification.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated, or relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

BMA proposes to relocate one existing dialysis station from BMA East Rocky Mount to Edgecombe Home Dialysis, an existing standalone kidney disease treatment center offering peritoneal dialysis (PD) training and support, for the provision of home hemodialysis (HHD) training and support.

In Section E, page 35, the applicant states its proposal is the most effective alternative because Edgecombe Home Dialysis currently offers home PD training and support, which does not need a dialysis station. For the applicant to offer HHD training, however, a dialysis station is needed. The applicant has identified HHD patients who will use the facility for their HHD training and support and who currently receive HHD services outside the county.

On page 35, the applicant states that if it is to offer its patients HHD training and support within Edgecombe County, the only option is to relocate a station as proposed in this application.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. FMS ENA Home Care, LLC shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, FMS ENA Home Care, LLC shall materially comply with the last made representation.**
 - 2. Pursuant to Policy ESRD-2, FMS ENA Home Care, LLC shall relocate one dialysis station from BMA East Rocky Mount to Edgecombe Home Dialysis for use as home hemodialysis training and support.**
 - 3. FMS ENA Home Care, LLC shall install plumbing and electrical wiring through the walls for no more than one dialysis station which shall include any isolation stations.**
 - 4. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify one dialysis station at BMA East Rocky Mount for a total of no more than 25 dialysis stations at BMA East Rocky Mount following completion of this project, Project I.D. #L-11374-17 (relocate ten stations to develop Fresenius Kidney Care Boice-Willis), Project I.D. #L-11483-18 (add four stations), and Project I.D. #L-11580-18 (add two stations).**
 - 5. FMS ENA Home Care, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

BMA proposes to relocate one existing dialysis station from BMA East Rocky Mount to Edgecombe Home Dialysis, an existing standalone kidney disease treatment center offering peritoneal dialysis (PD) training and support, for the provision of home hemodialysis (HHD) training and support.

Capital and Working Capital Costs

In Form F.1(a), Section Q, page 81, the applicant projects the total capital cost of the project, as shown in the table below.

| | |
|---------------------|----------------|
| Site Costs | \$0 |
| Construction Costs | \$0 |
| Miscellaneous Costs | \$3,750 |
| Total | \$3,750 |

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, page 38, the applicant states there are no start-up expenses or initial operating expenses associated with this project, because Edgecombe Home Dialysis is an existing facility and is currently operational.

Availability of Funds

In Section F, page 37, the applicant states that the capital cost will be funded as shown in the table below.

| SOURCES OF CAPITAL COST FINANCING | | |
|-----------------------------------|-------------------|----------------|
| TYPE | FMS ENA HOME, LLC | TOTAL |
| Loans | \$0 | \$0 |
| Accumulated reserves or OE * | \$3,750 | \$3,750 |
| Bonds | \$0 | \$0 |
| Other (Specify) | \$0 | \$0 |
| Total Financing | \$3,750 | \$3,750 |

* OE = Owner's Equity

Exhibit F-2 contains a letter dated January 15, 2020 from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., parent company to FMS ENA Home Care, Inc. authorizing the use of accumulated reserves for the capital needs of the project. The letter also states that the Fresenius Medical Care Holdings, Inc. 2018 consolidated balance sheets show \$1.8 billion in cash and total assets in excess of \$20 billion.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F-2, the applicant projects that revenues will exceed operating expenses in the first two operating years (OY) of the project. The applicant's OYs are calendar years (CY), as shown in the table below.

| | 1 ST INTERIM YEAR (CY 2019) | 2 ND INTERIM YEAR (CY 2020) | FIRST FULL OY (CY 2021) | 2 ND FULL OY (CY 2022) |
|---|---|---|----------------------------|--------------------------------------|
| Total # Treatments | 4,588.0 | 5,238.8 | 5,555.5 | 5,716.6 |
| Total Gross Revenues (Charges) | \$28,863,108 | \$32,957,480 | \$34,949,672 | \$35,963,113 |
| Total Net Revenue | \$2,400,704 | \$2,741,256 | \$2,798,272 | \$2,876,805 |
| Average Net Revenue per Treatment | \$523.26 | \$523.26 | \$503.69 | \$503.24 |
| Total Operating Expenses (Costs) | \$1,031,097 | \$1,234,884 | \$1,411,988 | \$1,450,076 |
| Average Operating Expense per Treatment | \$224.74 | \$235.72 | \$254.16 | \$253.66 |
| Net Income | \$1,369,607 | \$1,506,372 | \$1,386,284 | \$1,426,729 |

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

BMA proposes to relocate one existing dialysis station from BMA East Rocky Mount to Edgecombe Home Dialysis, an existing standalone kidney disease treatment center offering peritoneal dialysis (PD) training and support, for the provision of home hemodialysis (HHD) training and support.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “...the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell and Yancey counties.” Thus, the service area for this facility is Edgecombe County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 126 of the 2020 SMFP, there are four existing dialysis facilities in Edgecombe County, three of which are owned by the applicant or a related entity. In Section

G, page 41, the applicant states no other dialysis facility in Edgecombe County provides home hemodialysis training and support.

In Section G, page 41, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Edgecombe County. The applicant states it is not proposing to create new dialysis stations in the county; rather, it is proposing to relocate one existing dialysis station to provide necessary home hemodialysis training and support to Edgecombe County residents who desire home hemodialysis and who are appropriate candidates for it.

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant adequately demonstrates that none of the existing dialysis facilities in Edgecombe County offer home hemodialysis training and support.
- The proposal would not result in an increase in the number of dialysis stations in Edgecombe County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Form H, page 91, the applicant provides information about current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

| POSITION | CURRENT # FTEs JANUARY 2020 | PROJECTED FTEs* CY 2021, CY 2022 |
|----------------------------------|--------------------------------|-------------------------------------|
| Administrator | 1.00 | 1.00 |
| Home Training Nurse | 1.00 | 2.00 |
| Dietician | 0.30 | 0.50 |
| Social Worker | 0.30 | 0.50 |
| Maintenance | 0.10 | 0.10 |
| Administration / Business Office | 1.00 | 1.00 |
| FMC Director of Operations | 0.10 | 0.10 |
| In-Service | 0.10 | 0.10 |
| Chief Technician | 0.05 | 0.05 |
| Total | 3.95 | 5.35 |

Source: table, Form H page 91

*The applicant projects the same number of FTEs for each of the first two OYs

The assumptions and methodology used to project staffing are provided in Sections H and Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, page 43, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 43, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I, page 44, the applicant states the following ancillary and support services are necessary for the proposed services:

| EDGECOMBE HOME DIALYSIS – ANCILLARY AND SUPPORT SERVICES | |
|---|---|
| SERVICES | PROVIDER |
| Self-care training | Provided on site by applicant |
| Home training HH PD Accessible follow-up program | Provided on site by applicant |
| Psychological counseling | Referral to Vidant Health |
| Isolation – hepatitis | Provided on site by applicant |
| Nutritional counseling | Provided on site by applicant |
| Social Work services | Provided on site by applicant |
| Acute dialysis in an acute care setting | Referral to Vidant Health Edgecombe and Vidant Health in Greenville |
| Emergency care | Provided by facility staff until ambulance arrives |
| Blood bank services | Referral to Vidant Health |
| Diagnostic and evaluation services | Referral to Vidant Health |
| X-ray services | Referral to Vidant Health |
| Laboratory services | Provided on site by applicant |
| Pediatric nephrology | Referral to Vidant Health |
| Vascular surgery | Referral to Vidant Health |
| Transplantation services | Referral to Vidant Health |
| Vocational rehabilitation & counseling | Referral to NC DHHS Vocational Rehabilitation Services Raleigh |
| Transportation | Edgecombe County Department of Social Services or Angel Wheels |

Source: table on application page 44

The applicant provides supporting documentation in Exhibits I-1.1 through I-1.4.

In Section I, page 45 the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-3.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose to construct any new space to accommodate the dialysis station. The applicant states on page 47 that the project proposes minor renovation of 150 square feet of existing space. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the

State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 52, the applicant provides the historical payor mix during CY 2018 for its existing services, as shown in the table below:

| EDGECOMBE HOME DIALYSIS HISTORICAL PAYOR MIX CY 2018 | |
|--|----------------------------|
| PAYMENT SOURCE | % TOTAL PATIENTS (PD ONLY) |
| Self-Pay | 2.44% |
| Medicare* | 44.42% |
| Medicaid* | 3.69% |
| Insurance* | 39.37% |
| Medicare/Commercial | 8.25% |
| Misc. (including VA) | 1.83% |
| Total | 100.00% |

*Includes managed care plans

In Section L, page 51, the applicant provides the following comparison.

| | PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY | PERCENTAGE OF THE POPULATION OF THE SERVICE AREA |
|-------------------------------------|---|--|
| Female | 60.0% | 53.8% |
| Male | 40.0% | 46.2% |
| Unknown | | |
| 64 and Younger | 52.5% | 80.3% |
| 65 and Older | 47.5% | 19.7% |
| American Indian | | 0.8% |
| Asian | 0.0% | 0.3% |
| Black or African-American | 87.5% | 57.8% |
| Native Hawaiian or Pacific Islander | 0.0% | 0.1% |
| White or Caucasian | 10.0% | 36.3% |
| Other Race | 2.5% | 4.7% |
| Declined / Unavailable | 0.0% | |

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 53, the applicant states:

“Fresenius related dialysis facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. Fresenius related facilities are responsible, and do provide care to both minorities and handicapped people.”

In Section L, page 53, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 54, the applicant projects the following payor mix for the proposed services during the second full operating year following project completion, as shown in the table below:

| EDGECOMBE HOME DIALYSIS PROJECTED PAYOR MIX CY 2021 | | |
|---|----------------------|---------------------|
| PAYMENT SOURCE | % TOTAL HHD PATIENTS | % TOTAL PD PATIENTS |
| Self-Pay | 0.62% | 2.44% |
| Medicare* | 65.74% | 44.42% |
| Medicaid* | 3.26% | 3.69% |
| Insurance* | 18.20% | 39.37% |
| Medicare/Commercial | 7.69% | 8.25% |
| Misc. (including VA) | 4.48% | 1.83% |
| Total | 100.00% | 100.00% |

*Includes managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.44% of total PD services will be provided to self-pay patients, 44.42% to Medicare patients and 3.69% to Medicaid patients. The applicant projects that 0.62% of total HHD services will be provided to self-pay patients, 65.74% to Medicare patients and 3.26% to Medicaid patients.

On page 54, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- It is based on the applicant's historical experience in its facilities in Eastern North Carolina, from which the applicant states it relied upon a wide-ranging geographic area to offer a more realistic projection of home hemodialysis revenues.
- It is based on the applicant's historical experience with actual home hemodialysis treatment volumes.
- Projected utilization is reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L, page 55, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M, page 56 and in supplemental information, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

BMA proposes to relocate one existing dialysis station from BMA East Rocky Mount to Edgecombe Home Dialysis, an existing standalone kidney disease treatment center offering peritoneal dialysis (PD) training and support, for the provision of home hemodialysis (HHD) training and support.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “...*the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell and Yancey counties.*” Thus, the service area for this facility is Edgecombe County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 126 of the 2020 SMFP, there are four existing dialysis facilities in Edgecombe County, three of which are owned by the applicant or a related entity. In Section G, page 41, the applicant states no other dialysis facility in Edgecombe County provides home hemodialysis training and support.

In Section N, pages 57 - 59, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. On page 57, the applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Edgecombe County. The applicant does not project to serve dialysis patients currently being served by another provider. ...

...

Fresenius related facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients’ lives by offering a convenient venue for dialysis care and treatment, and promoting access to care.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections C, G, K, L, N and Q of the application and any exhibits).
- Quality services will be provided (see Sections C, G, N and O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections C and L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 114 dialysis facilities located in North Carolina.

In Section O, page 63, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care resulting in an immediate jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 114 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of

health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicant proposes to relocate one existing dialysis station from BMA East Rocky Mount to Edgecombe Home Dialysis for the purpose of providing home hemodialysis training and support in a facility that currently exclusively serves PD patients. The Criteria and Standards for End Stage Renal Disease Services, promulgated in 10A NCAC 14C .2200, are not applicable to this review due to a declaratory ruling issued by the Agency on October 10, 2018, which exempts the Criteria and Standards from applying to proposals to develop or expand facilities exclusively serving HHD and PD patients.